



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF
PATENT APPEALS AND INTERFERENCES

Attorney Docket No. 24741-1525

In re patent application of

Jan C. SIMON *et al.*

Serial No.: 09/856,694

Filed: August 13, 2001

Art Unit: 1651

Examiner: Davis, Ruth A.

For: HYPERFORIN AS CYTOSTATIC AGENT AND HYPERFORIN OINTMENT
OR CREAMS AS APPLICATION FORM

REPLY BRIEF

Appeal from the Primary Examiner

Heller Ehrman LLP
1717 Rhode Island Avenue, NW
Washington, DC 20036-3001



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Appellants respond to the Examiner's Answer of May 20, 2005. This Reply is being filed before July 20, 2005. It is believed that no fees and no extensions of time are due with the submission of this brief. In the event any fees are required for the filing of this paper, please charge such fees to Deposit Account No. 08-1641.

I. REPLY TO EXAMINER'S ANSWER

- A. Whether claims 36-45 and 56 would have been obvious over The Hypericum Homepage (*Hypericum & Depression*, Bloomfield *et al.*, Copyright 1996, Prelude Press, Editor J. Sedillos) in view of *The Merck Manual* (1995-2002) within the meaning of 35 U.S.C. § 103(a).

In the Examiner's Answer, the Examiner relies upon the following statement in the last page of the cited Hypericum Home Page to support the case for obviousness: "Anti-inflammatory and antibacterial effects of externally applied St. John's Wort preparations have been reported and attributed to the presence of hyperforin (1)."

Appellants respond that this statement invites experimentation, which is not the standard for obviousness. This is so because St. John's Wort contains at least nine other ingredients and the quoted statement does not explain whether hyperforin was, in fact, the only ingredient applied in such "St. John's Wort preparation." The reference to which this statement alludes, i.e. "(1)" is, perhaps, a better reference from the standpoint of the PTO's case. However, the PTO has not cited reference "(1)" and the contents of this reference is not known. In fact, this reference may not support the PTO's case at all. Thus, Appellants maintain that the PTO has not met its burden.

The Examiner also maintains with regard to dependent claims 37 and 38 that all inflammatory diseases are the same. However, the PTO has failed to support such assumption.

- B. Whether claims 36, 38-45, and 56 would have been obvious over Valavichyus, "Antitumor Activity of Medicinal Plants from the Lithuanian SSR, USSR 6, Common St. John's Wort *Chamomilla Recutita*" (*Abstract from BIOSIS*, 1986) within the meaning of 35 U.S.C. § 103(a).

In the Examiner's Answer, the PTO has ignored the "consisting of" language in applicants' claims. The cited art teaches combinations of ingredients. Consequently, they should not be relied upon to suggest what applicants claim.

With regard to the issue of whether "oil extracts" are carriers, appellants respond that the meaning of pharmaceutically acceptable carrier is defined by reference to the present specification. Appellants have pointed out where the specification (i.e. page 19, last paragraph et seq.) shows that what the art teaches (oil extracts) is not effective for the claimed uses. Because terms are defined in view of the specification, appellants should not need to explicitly disclaim oil extracts in the claim.

- C. Whether claims 36, 38-45, and 56 would have been obvious over Valavichyus in view of HHP and/or DeCosterd, *Helvetica Chimica Acta*, 72:464-471 (1989) within the meaning of 35 U.S.C. § 103(a).

In the Examiner's Answer, the PTO points out that although claim 36 does not recite "cancer" the claims do recite types of cancer. Appellants clarify that DeCosterd has a very narrow teaching, i.e. the isolation of two new compounds, hyperevolutin A and hyperevolutin B from the root bark of *Hypericum revolutum* VAHL. These compounds showed growth inhibitory activity against *in vitro* colon carcinoma cell line. Such a report does not direct the skilled artisan to Appellants' invention, which relates to specific conditions (not a genus of all cancers) that are not suggested by DeCosterd's study, which is limited to colon cancer. At best, DeCosterd invites experimentation and further investigation; however, it does not support an obviousness rejection.

II. CONCLUSION

For these reasons, the Board is respectfully requested to reverse the examiner, pass the presently rejected claims on to allowance, and remand this application for issuance.

Respectfully submitted,

Date July 18, 2005

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Date	July 18, 2005

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